DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 11, 2014

iSYS Medizintechnik GmbH
c/o Mrs. Cornelia Damsky
56 Westcott Road
Stamford, CT 06902

Re: K131433
Trade/Device Name: iSYS 1
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Date: February 11, 2014

Dear Mrs. Damsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K131433

Device Name
iSYS 1

Indications for Use *(Describe)*
The iSYS 1 device is a user-controlled electromechanical arm with a needle guide. It is intended to assist the surgeon in the positioning of a needle or electrode where both computed tomography (CT) and fluoroscopic imaging can be used for target trajectory planning and intraoperative tracking. The needle or electrode is then manually advanced by the surgeon. Trajectory planning is made with software that is not part of the iSYS device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joyce M. Whang -S

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510(k) SUMMARY

1.	Applicant:	iSYS Medizintechnik GmbH
2.	Address:	Bergwerksweg 21 6370 Kitzbühel / Austria
3.	Contact Person:	Dr. Michael Vogele Tel. +43 (0) 664 2411140
4.	Preparation Date:	January 20, 2014
5.	Device Submitted:	iSYS 1 (U.S.)
6.	Proprietary Name:	iSYS 1 (U.S.)
7.	Common Name:	Robotic Positioning Unit
8.	Classification Name:	System, X-ray, Tomography, computed Product Code JAK, ~~MXX~~, Reg.No. 892.1750
9.	Substantial Equivalence:	The iSYS 1 is substantially equivalent to the following legally marketed devices: PinPoint manufactured by Philips Medical. The characteristics of this device are similar to those of the predicate devices identified on the comparison chart, which follows. It is our opinion that the iSYS 1 does not have technological characteristics that raise additional types of questions related to terms of safety and effectiveness.
10.	Device Description:	The iSYS 1 is a modular needle guidance platform for interventional radiology and related fields. Core components are a 4 DOF micro positioning unit which allows the submillimetric needle positioning from simple needle angulations up to positioning and angulations with adjustable pivot point and a control unit which is directed by a cable connected control panel. The passive macro positioning unit and different table adapters allow different setups of the system around the patient in the region of interest. The needle-guide-kit (manufactured by ECOLAB) provides disposable components that ensure precise and sterile needle guidance. Planning of the tool position/orientation as well as validation of the correctness of the tool position must be performed with an external planning and measurement system which is not part of the iSYS-1 Interventional Platform. The position of iSYS 1 is visible for most imaging systems due to the used markers. During treatment the tool is controlled by the

user.

11. Intended Use:

The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like.

12. Indications for Use

The iSYS 1 device is a user-controlled electromechanical arm with a needle guide. It is intended to assist the surgeon in the positioning of a needle or electrode where both computed tomography (CT) and fluoroscopic imaging can be used for target trajectory planning and intraoperative tracking. The needle or electrode is then manually advanced by the surgeon. Trajectory planning is made with software that is not part of the iSYS device

13. Clinical Use

The Side Rail Adapter is attached to the side rail for the setup; the Table Top Adapter is attached directly onto the CT table. Both Adapters are equipped with a "starburst" connector, to which the Multifunctional Arm (MFA) can be attached. The MFA is equipped with one "starburst" connector at the bottom and one "spoon" connector at the top. The "spoon" connector has its counterpart on the Robotic Positioning Unit for the setup. The Control Unit is attached directly to the side rail. The Robotic Positioning Unit is connected by a cable to the Control Unit, which has cable connections to both the electric power supply and to a Handheld Control Unit. The Needle Guide Extensions are screw-fixed onto the Robotic Positioning Modules. The Sterile Cover is directly fixed onto the Needle Guide Joints and can be drawn over the robotic parts. The Needle Insert is placed into the appropriate connector of the Needle Guide, to prepare needle usage. The Handheld Control Unit can be clamped onto the side rail and covered with a drape. Planning of the tool position/orientation as well as validation of the correctness of the tool position must be performed with an external planning and measurement system

(imaging or navigation software).

14. Biocompatibility:

The iSYS 1 is not in contact with patient. At any time when in use a sterile cover sheet is to be placed between the patient and the system. Additionally there are no new materials introduced in the manufacture of the iSYS 1. Therefore, no biocompatibility studies were performed for this device.

15. Performance Data:

Operating temperature/humidity range: 15 to 30°C; 30 to 70% relative humidity with no condensation

Storage temperature/humidity range: 10 to 50°C; 30 to 70% relative humidity with no condensation

Power Supply: 50W; 115VAC/230VAC; 50-60Hz; cable: C14 according to IEC/EN 60320-1, US498, CSA C22.2 no. 42;

Sterilization of the sterile accessories has been validated by Bioseal and Preferred Medical, the companies responsible for packaging and sterilizing the iSYS accessories.

The accuracy of the intervention depends on the resolution and capabilities of the imaging device or software. The mechanical accuracy of iSYS1 is below 1 mm, but that gives no accuracy value for treatments.

Device Comparison Summary:

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence ?
510k-Number	K974513	K131433	
Manufacturer	PHILIPS MEDICAL SYSTEMS (CLEVELAND), INC. 595 Miner rd. Cleveland, OH 44143 USA	iSYS Medizintechnik GmbH Bergwerksweg 21 A-6370 Kitzbuehel Austria	
Design			
General device description	Five jointed, position-sensing stereotactic arm, mounted on the CT gantry, and indicated for invasive procedures	Computer controlled electromechanical multi-joined arm indicated for invasive procedures	Yes
Localization means	Robot arm absolute encoders	Fiducial markers on tool holder.	*3)
Image-guided	Yes	Yes	Yes
Planning software	No, not cleared under this 510k (K955268)	No (third party)	Yes
Registration method	During installation	Fiducial markers	*4)
Instrumentation	Cannula Laser needle guide	Marker Tool Holder Sterile Covers (third party)	Yes
Instrument fixation	Cannula attached to the arm (optional: laser needle guidance)	Special tool holders for several applications mounted to the Robot	Yes
Instrument calibration	Factory Calibration Optional: intra operative	Intra operative	*1)
System immobilization between patient and device	Yes	Yes	Yes
Planning and Navigation Software			
N/A.			
System Operation			
Fiducial markers registration with	No	No	Yes

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence ?
pointer probe			
Optical registration	No	No	Yes
Ultrasound Registration	No	No	Yes
Accuracy verification	Yes, external anatomical verification	Yes, performed by user	Yes
Provide mechanical guidance for tools	Yes	Yes	Yes
Instrument guide position adjustment	Manual	Manual	Yes
Physician carries out final gesture through tool guide	Yes	Yes	Yes
Indications for Use			
Indication for use	The PinPoint is an accessory to a CT system intended to provide the radiologist with a means of simulating and initiating interventional procedures by interactively relating the patient's CT image volume to the actual target field. This accessory includes mounting the stereotactic arm on a CT-Gantry, a flat panel TV monitor, cabling, biopsy phantom and software. In addition the CT is intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data from	The iSYS 1 device is a user-controlled electromechanical arm with a needle guide. It is intended to assist the surgeon in the positioning of a needle or electrode where both computed tomography (CT) and fluoroscopic imaging can be used for target trajectory planning and intraoperative tracking. The needle or electrode is then manually advanced by the surgeon. Trajectory planning is made with software that is not part of the iSYS device.	Yes

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence ?
	the same axial plane taken at different angels. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories. PinPoint is not limited to any particular region of the body. It is equally viable for planning head and spine interventions as it is in the abdomen. It is expected that its major use will be in the planning of biopsies of abdominal organs and drainage of fluid collections in the abdomen. However, more complicated procedures such as Brachy therapy and bone pinnings will be planned using the PinPoint.		
Intended Use	The PinPoint is an accessory to a CT system intended to provide the radiologist with a means of simulating and initiating interventional procedures by interactively relating the patient's CT image volume to the actual target field. The system produces cross sectional images by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. A stereotactic arm on a	The intended use of the iSYS1 device is to function as a remote-operated positioning and guidance system during interventional procedures. Positioning is done in remote control manner; planning of the position/angulation is done based on 2D/3D patient data (CT, cone-beam CT, fluoroscopy) by external planning software – for example using an external navigation system, or planning software coming with the used imaging device. Also	Yes

Reference	PinPoint	iSYS 1 (for new submission)	Equivalence ?
	CT Gantry, a flat panel TV monitor, and biopsy phantom are used as accessories to produce these images. The primary intend of the system is to provide guidance for biopsies in the abdomen, spine and head.	verification of the correct position and orientation of the tool prior to/during/after the intervention is done by means of these external devices. The iSYS1-System is then acting as a guideway during the manual insertion of the interventional tool – usually a needle type device, and the like.	
Anatomical site	Total Body	Total body	Yes
User	Radiologist	Physician	*2)
Accessory	V-Channel Cannula Cylindrical Cannula	Sterile Covers Table Adapters Cable Sets	Yes
Real-time instrument position	Yes	Yes	Yes
Mechanical Guidance of instruments	Yes	Yes	Yes
Technology			
Powered	Yes	Yes	Yes
CE-Conformity	No	Yes	Yes
Computer-controlled	Yes	Yes	Yes
Materials	Metal, electronics and plastics	Metal, electronics Polyamide Polyethylene Bralen	Yes

Similarities and Differences:

All three devices are intraoperative instruments used by physician for assisting the spatial positioning and orientation of a surgical tool.

iSYS 1 is equivalent to:

- PinPoint for assisting the spatial positioning and orientation of a surgical tool.
- PinPoint for being localized by the navigation or imaging software.
- PinPoint for being guided by an imaging device
- PinPoint for providing a registration method for the imaging device.
- PinPoint for instrumentation and instrument fixation.
- PinPoint for being immobilized in relation to the patient.
- PinPoint for providing accuracy verification, tool guidance and position adjustment.
- PinPoint for the physician making the final gesture.
- PinPoint for having the same indications for use and region of interest.

Differences:

*1) PinPoint provides a factory instrument calibration of the encoders. During intervention the physician using iSYS1 and PinPoint verifies the position of the needle or needle-type instrument (tool). Verification of the tool position requires greater physical effort but provides for exact (depending on the imaging system) tool localization. The localization of the tool is not required for the iSYS 1 and, thus, this has no effect on safety or effectiveness.

*2) While the PinPoint is indicated to be used by radiologists only, the iSYS 1 is indicated to be used by any trained physician. This has no effects on safety and effectiveness.

*3) PinPoint provides encoders for localization, whereas iSYS uses fudicial markers on the tool. Using fiducial markers provides better localization safety.

*4) While the Pinpoint is registered during installation, the iSYS 1 uses fiducial markers for registration. Again, using fiducial markers provides better localization safety.

Non-Clinical Performance Data:

Non-clinical testing has mainly been performed to prove electrical and mechanical safety of the devices. Similar to the predicate devices, iSYS 1 was tested according to EN ISO 60601-1 2nd edition:

- EN 60601-1:1990 + A1:1993 + A2:1995
- EN 60601-1-8:2004 + A1:2006

The Electromagnetic Compatibility of the iSYS1 System has been tested according to FCC Part15 (Edition 1st October 2010) and ISO 60601-1-2:2007 and meets the acceptance criteria of both.

Performance tests have been performed to prove:

- the accuracy of the needle placement under clinical conditions,
- the compatibility with the imaging modality,
- the tendency to produce artifacts,

- the mechanical stability of the system despite external payload under worst conditions
- the mechanical stability of the table adapters despite external payload,
- the accuracy in remote-control mode
- the accuracy of needle guidance
- functionality of hardware modules
- effectiveness of hardware safety measures for the software,
- and the effectiveness of the alarm systems

The results of these performance tests support that the predicate devices and iSYS 1 are substantially equivalent.

Conclusion:

It is our opinion that the iSYS 1 System (U.S.) does not have technological characteristics that raise additional types of safety or effectiveness questions, and we consider them to be an enhancement to the existing devices.

To validate the accuracy of the iSYS 1 an external reference system has to be used. We have used and validated the accuracy of the iSYS 1 System (U.S.) with the Philips Allura Xper Guide FD 20 X-ray system and the Axiom Artis Zeego from Siemens Healthcare, and passed all tests.